May 9, 2017

Governor Chris Christie
Office of the Governor
PO Box 001
Trenton, NJ 08625

Dear Governor Christie,

It is well documented the opioid epidemic was brought on by well-intentioned but misguided and uninformed actions by physicians and our healthcare and health insurance systems. This started with the change in prescribing practices initiated by FDA approval of OxyContin in 1995. From 1999-2014, annual prescriptions of opioid prescriptions increased fourfold. Tragically, this caused a fourfold increase in overdose deaths caused by opioids, with no improvement in pain or function.

This epidemic is taking more than 100 of our loved ones lives every day. In addition, it is estimated that the opioid epidemic costs our society ~$78 billion per year in healthcare costs, lost productivity, and criminal justice. If this were an outbreak of Zika or Ebola, resources would be unlimited and people would be working around the clock to implement practical solutions.

We respectfully submit the following evidence-based recommendations, which are based upon the urgency and resources consistent with the continuing growth of this epidemic. We believe, when fully implemented, they will reduce the number of deaths and cost to our society by more than two-thirds in just a few years. This can be done quickly and efficiently.

We would also like to emphasize two points. Of the approximate 30 recommendations that follow, approximately 20 of these do not require any funding; rather simply efficient implementation. And of the approximate 10 that do require funding, the ROI on each of these to our society is far, far greater than needed to justify their expenditure.

Treat and Save ~5 million Americans currently afflicted with an Opioid Use Disorder (OUD)

1. Access to Treatment

   The most potent but often unused or misused weapon to reduce overdose and to increase treatment penetration is properly applied Medication Assisted Treatment (MAT). There is an enormous gap in the United States in capacity to treat opioid use disorder compared with the need, and ~80% of those with an OUD are not treated. Providing the right medications at the right dose and supervised in the right way can be achieved rapidly. We can increase the number of opioid addicted individuals who are now untreated to achieve at least 80% within **months** with the following recommended tactics:

   a. Presidential Executive Order issued to achieve the 80% benchmark by December 31, 2017.

b. Map those with a Substance Use Disorder (SUD), overlaying doctors certified to prescribe, and filling the gaps with emergency training/certification. The cost of this emergency training will be covered by the federal government (emergency spending via Presidential Order).

c. Reduce the number of required training hours from eight to no more than three, or possibly eliminate the training completely. Buprenorphine has a lower risk profile than do full agonist opioids. While there are important considerations to be aware of in its use, it is not more complicated to prescribe than many other medications that providers prescribe regularly without required training, such as insulin or warfarin.

d. Consider requiring that all providers who prescribe opioids are equipped to manage opioid-related adverse outcomes that might affect their patients, including opioid use disorder (and, therefore, the ability to use medication-assisted treatment as a routine part of medical care).

There is precedent for this – England. In 2000, England had the highest rates of untreated opioid addiction in Europe (94% of known opioid addicted individuals were untreated) and were threatened with the potential for massive increases in AIDS and Hepatitis C. The public health department trained and incentivized primary care physicians to screen and engage addicted individuals into treatment. This was accompanied by a massive public health information campaign that took the stigma away from being addicted and transferred it to not being in treatment. Within two years, over 65% of known opioid addicted individuals were under treatment, rates of new opioid addictions had fallen by 45%, and England still has the lowest rates of AIDS and Hepatitis in Europe.

We now have more and better medications and a much broader system of public health. This is a practical, realistic, efficient way to stop overdoses, reduce costs and stop new addictions.

A large portion of the cost of this medication will be provided by existing financing channels. All FDA approved medications for opioid treatment (methadone, buprenorphine, naltrexone) are already covered by Medicare, Medicaid, VA, Indian Health Service, and most private insurers in virtually all states. Any gap in coverage could be provided by the federal government (emergency spending via Presidential Order in 2017, and within federal budget starting Oct 1, 2018).

We also recommend that funding of the federal SAMHSA block grants to states be contingent upon acceptance by state authorities of appropriately prescribed and monitored use of MAT for those with an OUD.

Two important additional components of MAT also need to be broadly implemented with the new prescribing: concurrent behavioral therapy (counseling to address underlying issues) and urine drug screen monitoring to assure safe usage and to minimize diversion. Both components of modern care management are well known to improve the quality and the public health benefits of addiction treatment, but funding cuts have minimized their use and there are simply not enough adequately trained professionals at this time. Thus, enhancing provision of these two important components will take longer than a few months. With the current uncertainty surrounding health insurance, we recommend that a plan to fill this gap be drafted by the administration by July 1, with implementation to begin immediately thereafter. We are not sure of the best implementation lever; however, we suspect with the appropriate urgency and resources this gap can be filled in **18 months**.

Lastly, it goes without saying that full enforcement of the *Mental Health Parity and Addiction Equity Act* needs to be accomplished. Numerous recent reports indicate there has been significant progress, however these reports also indicate much more needs to be done. **Full** compliance with this law is essential, and needs to be achieved. As is recommended throughout this letter, as President Reagan did related to getting speed limits to 55 miles per hour, using the incentive of federal funding to states is a lever we recommend.

2. Quality of Treatment

Well-supported scientific evidence shows that substance use disorders can be effectively treated, with recurrence rates no higher than those for other chronic illnesses such as diabetes, asthma, and hypertension. **However, treatment for substance use disorders, and OUD specifically, is most often delivered for only minimal periods and without the use of evidence-based quality measures**.

In 2006, the Institute of Medicine published a report, *Improving the Quality of Health Care for Mental and Substance-Use Conditions*. This report urged HHS, in partnership with the private sector, to direct and financially support an entity to convene government regulators, accrediting organizations, consumer representatives, providers, and purchasers with the purpose of reaching consensus and implementing a common, continuously improving set of M/SU health care quality measures for providers, organizations, and systems of care to follow. Participants in this consortium should commit to:

- Requiring the reporting and submission of the quality measures to a repository of performance measures.
- Requiring validation of the measures for accuracy and adherence to specifications.
- Ensuring the analysis and display of measurement results in formats understandable by multiple audiences, including consumers, those reporting the measures, purchasers, and quality oversight organizations.
- Establishing models for benchmarking and quality improvement purposes at sites of care delivery.
- Performing continuing review of the measures' effectiveness in improving care.

These recommendations have not been implemented. Shatterproof recently began a process to do so privately - See Exhibit A: *SUD Treatment Task Force Executive Summary*. We recommend that pursuant to the IOM recommendation, HHS become involved as soon as practical to accelerate this initiative.

3. Rescuing those Experiencing an Overdose

If administered in time, naloxone can save lives and give people a second chance so they can get into treatment or take other actions to reduce their risk. It is inexpensive and effective to administer, has essentially no side effects on individuals or the public at large and must be incentivized for much broader availability. Particularly in college health centers, ERs, prison and jail health clinics, and by primary care physicians who provide the greatest proportion of opioids for treatment of pain.

Through Governor Proclamations, state legislation and state regulation, states are gradually expanding access by making naloxone available by pharmacists without doctor prescriptions and providing indemnities to those able to administer this medication in an emergency. However, progress is far too slow. In 2016 Shatterproof documented nine best practices each state should implement (see Exhibit B), and then scored each state. The scores indicate much is left to be accomplished.

We recommend four levers to accomplish:

a. HHS recommends that every first responder in the US become trained and stocked with naloxone by September 1, 2017. Paid for by the federal government. Any state which has not accomplished this by November 1, 2017 will not have access to any funding in 2018 from the federal government from SAMHSA block grants, CARA funding, the 2nd $500,000 of the 21st Century Cures Act, and other funding channels TBD.

b. HHS recommends that every state enact legislation and/or regulations that comply with the nine best practices, with a stipulation that any state which has not accomplished this by February 28, 2018 will not have access to any funding in 2018 from the federal government from SAMHSA block grants, CARA funding, 2nd $500,000 of the 21st Century Cures Act, and other funding channels TBD.

c. The federal government consider supporting the FDA in making naloxone an over-the-counter drug to increase accessibility. We have yet to list the advantages and disadvantages of this.

d. The federal government leverages its purchasing power on behalf of states to counter recent dramatic increases in price that threaten local supply in the face of surges in overdose.

4. Provider Education

7% of medical schools mandate any courses in substance use disorders. This leaves those who will ultimately prescribe opioids and who will encounter the health effects of opioid and other substance use disorders in their practices utterly unprepared to provide safe, effective care. Meanwhile, the federal government provides literally every medical and nursing school in our country with billions of dollars in low-cost loans for student tuition. Without any additional funding, it would immediately be possible to require that medical and nursing students who wish to use those federal funds attend a school that has at least one approved course in addiction. The immediate effect would be that all medical, nursing, dental, and likely other related professional schools would adopt existing courses that they have until this point ignored. There are approved, online courses for second year medical and nursing students and there are well structured residency training programs available through ASAM – these simply have not been used by the schools.

5. Prison Population

One of the populations most at risk for overdose death in this country are the 30 – 40% of inmates who will be released from federal/state prisons and community jails who were incarcerated for opioid related crimes. Approximately 250,000 inmates a month. Not only are they at personal risk for overdose and relapse– they are a significant vector for the spread of opioid misuse in the communities to which they will return. Treatment as a condition of community release is a well-established practice and has been since the mid-1990s. But with little training of community corrections officers, problems with insurance (including Medicaid) among those released, and caseloads of over 500 per corrections officer, these well-intentioned efforts have not been effective. But they could be. It is not the idea that is lacking – it is the execution. Caseloads need to come down, training in addiction monitoring and management needs to go up. More use of therapeutic monitoring of drug use must increase (where a drug positive test does not result in automatic return to incarceration, but instead to increased intensity of treatment, monitoring, and supervision). Again, there are precedents and they have worked. This was one of the key provisions in the overhaul of Portugal's drug policy that saved money in re-arrest, re-trial, and re-incarceration and improved public safety.

6. End the Shame, Isolation, and Stigma

The stigma that is associated with those afflicted with OUD is unjust and needs to end. Societal stigma inhibits resources applied to this disease that are indicated by both its cost in human suffering and its cost to our society. Societal stigma leads to self-stigma, further increasing the human and societal costs of this disease. We recommend President Trump lead the way in ending the stigma of this disease with his messaging and prioritization of our resources.

Prevent our 320 million Americans and future generations from developing an OUD

7. FDA Labeling of Opioids

   Opioids are one of the only medication classes that lack a suggested maximum dose on its FDA-approved label. Even over-the-counter medications include a suggested upper dose. Another problem with opioid labels is that they are too broad, allowing opioid makers to promote use for conditions where risks outweigh benefits. FDA can promote more cautious prescribing through improved labeling, and we recommend President Trump issue a Presidential Executive Order, or the levers of his influence, to ensure this occurs no later than September 1, 2017.

8. Effective Use of PDMPs

   Per the CDC, PDMPs are among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. However, in 86% of prescriptions for opioids written in 2015, the patient history was not checked by the prescriber. In March 2017, Shatterproof published *Prescription Drug Monitoring Programs: Critical Elements of Effective State Legislation*, detailing 12 recommendations (see enclosure). Each state has recently been scored, and the scores indicate much is left to be accomplished. We recommend the following:

   a. Federal government recommends that every state enact legislation and/or regulations that comply with these 12 best practices, with a stipulation that any state which has not accomplished this by February 28, 2018 will not have access to any funding in 2018 from the federal government from SAMHSA block grants, CARA funding, the 2nd $500,000 of the 21st Century Cures Act and other funding channels TBD.

   b. CMS require that all Part D plans include a prior authorization requirement which would state that prescribing physicians must attest that he/she has checked the state PMDP prior to prescribing any drug in Schedule II, III, or IV.

   c. Reporting of each patient drug overdose becomes the 13th recommendation.

   d. PDMPs incorporate universal use, real time, actively managed, and easy to use and access features. Consider the cost/benefit of a national PDMP to replace state PDMPs. This could be accomplished with a national system with certain required features, along with additional features decided by each state.

9. Mandatory Provider Education

   We recommend an amendment to the Controlled Substance Act whereby all DEA registrants are required to take a course in the proper treatment of pain by December 31, 2017, and then on a rolling basis, as part of their regular on-going renewal. This course, prepared by HHS, by October 1, 2017 includes CDC training on *Prescribing Opioids for Pain*. We recommend that it be strongly considered that providers who intend to prescribe more than a 3-day supply of opioids have a requirement to take this course. Many will not do so, limiting the pool of prescribers allowed to give more than 3-day supply. And those that opt-in should have no issue taking a comprehensive course. Alternatively, this may be able to be accomplished by Presidential Executive Order.

10. Patient Education

We recommend an amendment to the Controlled Substance Act whereby every time a prescription is written for greater than three days the prescriber must have the patient sign a consent form explaining the risks and benefits. Alternatively, this may be able to be accomplished by Presidential Executive Order.

11. Implementation of CDC Guideline

On March 15, 2017, the CDC issued the *CDC Guideline for Prescribing Opioids for Chronic Pain*. In the recommendations above we have provided for implementation of four of the 12 recommendations; dosage, use of PDMP, deadly combinations of opioids and benzodiazepines, and patient information of risks and benefits. Our recommendations do not encompass the remaining eight, and therefore we recommend identifying a way to ensure implementation of the entire Guideline. The quickest and most efficient way to do so would most likely be Recommendation #10 above. Other potential tactics could include:

a. Medicare Part D to raise the cap on speech and physical therapy. Currently at $1,960, it is too low and discourages prescriptions for physical therapy.

b. CMS incorporates the CDC Guideline into the Conditions of Participation (CoPs) for the Medicare and Medicaid programs. Such reliance on the CDC Guideline is fully consistent with the purpose of CoPs, which serve as standards to protect the health and safety of beneficiaries and to ensure the quality of their care. CMS can work closely with providers, health systems, and state agencies, and HHS can provide a wealth of guidance as well as technical assistance to State Medicaid programs nationwide. This step would impact all healthcare organizations that participate in CMS.

c. CMS Part D plans put in a prior authorization requirement which would state that prior to the prescribing of any opioid for longer than three days, an Informed Consent Form must be signed by the patient, or CMS would impose a requirement that all Part D plans include a prior authorization requirement which would state all prescribers must take the soon to be issued CDC online course in the CDC Guideline for Prescribing Opioids for Chronic Pain and adopt as a standard of care.

d. Food and Drug Administration (FDA) should incorporate the CDC Guideline into its "Blueprint" for prescriber education on extended-release and long-acting opioid analgesics. Once the CDC Guideline is finalized, the FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program for prescription opioids must be immediately updated to reflect what will be the most up-to-date regulatory science and clinical guidance.

e. Performance Measures. HHS should begin work through CMS, the Center for Medicaid and Medicare Innovation (CMMI), CDC, the Agency for Healthcare Research and Quality (AHRQ), and its other agencies, to develop and evaluate performance measures for adoption of the Guideline through annual Medicare and Medicaid payment rules, in Accountable Care Organizations (ACOs), as well as in other innovative value-based payment pilots.

f. Academic detailing or other quality improvement protocols to educate providers on guideline-recommended practices.

g. Mechanisms should also be considered to reach providers and patients in underserved areas, such as in rural and tribal areas, including telehealth and telemedicine strategies.

12. Additional Prescribing Guidelines

    The CDC Guideline is related to primary care, and as primary care only covers ~50% of opioids prescribed, guidelines need to be issued for all other prescribers. We recommend that temporary guidelines for these additional prescribers be issued by December 31, 2017, and then improved guidelines reissued by December 31, 2018. If this were an Ebola outbreak, people would not be waiting for the perfect guidelines, our experts would be getting something out and working to improve it over time.

13. Data, Accountability

    Require payers (e.g., Medicaid, Medicare) and Prescription Drug Monitoring Programs (PDMPs) to provide feedback to providers on prescribing metrics, focusing on providers with high-risk prescribing histories (e.g., provide letters to inform of high-risk prescribing practices, with references to guidelines and education available). Further recommendations on this will be forthcoming.

ONDCP

The administration's current draft budget includes cutting 95% of the ODCP budget. We strongly recommend the ONDCP budget not be cut. In addition, we recommend the Director of this agency/office be elevated to a cabinet level position, and its authority altered to be consistent with this role.

Healthcare Insurance

The bill passed by the House takes several steps backwards on combating the opioid epidemic. We recommended that President Trump not support any bill that reduces insurance benefits in the aggregate for Americans who need treatment for a substance use disorder or mental illness.

Sunset Provisions

Shatterproof believes it is important not to overregulate our healthcare industry. In this regard, several of our recommendations should include provisions that end the specific requirement once both the number of those addicted and those dying drop below defined thresholds. Recommendations related to PDMPs could sunset based on achieving certain benchmarks.

Thank you for your consideration of these recommendations. We believe these recommendations represent systematic, comprehensive, and promising federal strategy to better protect the lives and health of Americans.

Sincerely,

Gary Mendell
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Exhibit A
Substance Use Disorder Treatment Task Force

The Issue

It is estimated that approximately 21 million Americans have a Substance Use Disorder (SUD):

- The combination of the misuse of alcohol and drug overdoses took the life of approximately 140,000 Americans in 2015.
- Drug overdoses related to opioids have increased five times in the last 15 years, and drug overdoses now exceed car accidents as the number one cause of injury death.
- The cost to our society in lost productivity, healthcare costs, and criminal justice exceed $400 billion per year.
- And beyond this cost, a recent study showed that the presence of a substance use disorder often doubles the odds for the subsequent development of chronic and expensive medical illnesses, such as arthritis, chronic pain, heart disease, stroke, hypertension, diabetes, and asthma.

Well-supported scientific evidence shows that substance use disorders can be effectively treated, with recurrence rates no higher than those for other chronic illnesses such as diabetes, asthma, and hypertension. **However, treatment for SUD is often delivered without the use of evidence-based quality measures**:

- Well-supported scientific evidence shows that medications can be effective in treating serious substance use disorders, but they are under-used.
- Well-supported scientific evidence shows that behavioral therapies can be effective in treating substance use disorders, but most of these are often implemented with limited fidelity and are under-used.

What is Different About this Task Force / Mission

There are numerous reports that provide the evidence of what treatment and recovery services should include, and recommendations of what should be done to improve the quality of treatment.

This Task Force is different. It has been formed to **ensure implementation** of the most up-to-date research findings to boost the quality/quantity of treatment (ultimately, improving patient outcomes). It is taking a business approach to this broad, public crisis with the foundation that "what does not get measured, often does not get done."

Background Documents

The Surgeon General of the United States issued a landmark report in November 2016 titled *Surgeon General's Report on Alcohol, Drugs, and Health*. This report included detailed information and recommendations related to the treatment of addiction.

In 2006, the Institute of Medicine published a report titled *Improving the Quality of Health Care for Mental and Substance-Use Conditions*. This report urged the Department of Health and Human Services, in partnership with the private sector, to direct and financially support an entity to convene government regulators, accrediting organizations, consumer representatives, providers, and purchasers with the purpose of reaching consensus and implementing a common, continuously improving set of M/SU healthcare quality measures for providers, organizations, and systems of care to follow.

Participants in this consortium should commit to:

1. Requiring the reporting and submission of the quality measures to a repository of performance measures.
2. Requiring validation of the measures for accuracy and adherence to specifications.
3. Ensuring the analysis and display of measurement results in formats understandable by multiple audiences, including consumers, those reporting the measures, purchasers, and quality oversight organizations.
4. Establishing models for benchmarking and quality improvement purposes at sites of care delivery.
5. Performing continuing review of the measures' effectiveness in improving care.

Approach

The approach of this Task Force will be to combine the content and recommendations of the two reports outlined above in the following steps:

1. Bring together a subset of its Task Force and others to gain consensus on a select number of quality measures that have strong evidence in improving patient outcomes and whose success and usage can be measured.

2. Bring together a subset of its Task Force and others to decide upon the prioritization of the levers of implementation described below.

3. Bring together a subset of its Task Force and others, and finalize a tactical plan to ensure implementation of evidence-based treatment.

Levers of Implementation

This Task Force views the following channels as levers of implementation:

1. Tie the use of evidence-based quality measures and/or patient outcomes to the state licensing of providers;
2. Payers of treatment provide incentives to providers for the use of evidence-based quality measures and/or patient outcomes;
3. Educate consumers to boost demand for evidence-based treatment quality measures and/or patient outcomes; and/or
4. Improve the education of providers in quality measures to improve provider satisfaction and improved outcomes.

When considering incentivizing providers, the Task Force reviewed estimates of 2014 spending on SUD Treatment ($34 billion) and its distribution of spending by payer:

- 29% State and Local
- 21% Medicaid
- 18% Private Insurance
- 12% Other Federal
- 19% Various smaller categories

Process

1. Quality measures finalized as a National Standard of Care.
2. Measurement System in place.
3. Levers of Implementation prioritized.
4. Implementation.

Phoenix Marketing Services has been retained to plan, organize, and facilitate the process. Their process will result in a document with Action Items, measurable by outcome and dates, outlining those responsible for getting each action accomplished. Shatterproof will lead the effort to coordinate completion of the Action Items and document measurable results.

Current Steering Committee

- Michael Botticelli, Executive Director of the Grayken Center for Addiction Medicine at Boston Medical Center, and former Director of Office of National Drug Control Policy.
- Jay Butler, President, ASTHO Board of Directors and Director of Public Health, Alaska Department of Health and Social Services.
- David Calabrese, SVP and Chief Pharmacy Officer, OptumRX
- Chris Hocevar, MBA, President of both Cigna Healthcare's Select and Pharmacy businesses.
- Charles Ingoglia, MSW, Senior Vice President, Public Policy and Practice Improvement at the National Council of Behavioral Health.
- Thomas McLellan, PhD, founder and chairman of the Treatment Research Institute, and served as the Deputy Director of the Office of National Drug Control Policy under President Obama.
- Gary Mendell, MBA, founder and CEO of Shatterproof, a national non-profit dedicated to reducing the devastation associated with addiction.
- Penny S. Mills, MBA, Executive Vice President / CEO, American Society of Addiction Medicine.
- Robert Morrison, Director, The National Association of State Alcohol and Drug Abuse Directors, Inc.
- John O'Brien, Senior Consultant at Technical Assistance Collaborative, Inc., former senior advisor at for healthcare financing at the U.S. Department of Health and Human Services.
- Daniel Polsky, PhD, Executive director of the Leonard Davis Institute of Health Economics. LDI is the leading university institute dedicated to improving health and health care through data-driven, policy-focused research. $100 million/year in research grants among 240 Senior Fellows.
- Martin H. Rosenzweig, MD, Senior Medical Director, Optum Behavioral

Exhibit B
Naloxone Best Practices

1. Prescription by standing order to laypersons authorized.

2. Prescriptions authorized to 3rd parties.

3. Prescribers have immunity from civil liability for prescribing, dispensing or distributing naloxone to a layperson.

4. Dispensers have civil immunity for prescribing, dispensing or distributing naloxone to a layperson.

5. Laypersons have immunity from civil liability for administering naloxone.

6. The law removes criminal liability for possession of naloxone without a prescription.

7. Pharmacists allowed to distribute naloxone via Standing Order, Protocol Order, Collaborative Practice Agreement or Pharmacist Prescriptive Authority.

8. Persons or organizations not otherwise permitted to dispense prescription medications permitted to possess, store, and dispense naloxone.

9. The law mandates insurance coverage for at least one form of naloxone.